IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:	Art Unit: 1614
Esmond *et al.*	Examiner: Kim, V.
Appl. No. 09/394,712	Atty. Docket: 0609.4440002/RWE
Filed: September 13, 1999	
For: **Method for Treating or Preventing Alzheimer's Disease**	**Batch No. A22**

#12

OK to grant petition. mcs 2/7/02

Petition Under 37 C.F.R. § 1.313(a) To Withdraw An Application From Issue For Interference Purposes

Commissioner for Patents
Washington, D.C. 20231

John J. Doll
Director, Technology Center 1600

Sir:

A Notice of Allowability (Paper No. 11) was mailed in the captioned application on January 3, 2001. It is hereby petitioned under 37 C.F.R. § 1.313(a) that the above-captioned application be withdrawn from issue. As payment of the issue fee has not yet been made, or is being made herewith, Applicants respectfully submit that filing under 37 C.F.R. § 1.313(a) is proper. *See* MPEP § 1308. As discussed below, Applicants respectfully request that the captioned application be withdrawn from issue for interference purposes. *See* MPEP § 1308.02.

The required petition fee under 37 C.F.R. § 1.17(h) of $130.00 is enclosed herewith.

I. Reason for Withdrawing From Issue

Filed herewith is a Request For Interference Under 37 C.F.R. § 1.607(a). As explained in the Request For Interference, it is believed that Applicants are entitled to a judgment of priority of invention over the patentees in U.S. Patent No. 6,191,154 ("the '154

patent," Attachment 1), which issued from application no. 09/200,700, filed November 27, 1998.

The captioned application is a continuation of International Application no. PCT/US98/04731 filed March 12, 1998 (abandoned), which claims the benefit of U.S. Provisional Application No. 60/039,607, filed March 12, 1997. The allowed claims in the captioned application are entitled to a priority date of March 12, 1997. Thus, Applicants have a date of priority which is more that 20 months before the date of priority of the '154 patent.

The U.S. Patent and Trademark Office should be interested in issuing only one patent that claims a given subject matter. However, if the captioned application is not withdrawn from issue, it will issue and more than one patent will exist that claims the same subject matter.

II. The Claimed Subject Matter

Claims 1, 2, 7, 8 and 13-29 are pending in the captioned application. A copy of claims 1, 2, 7, 8 and 13-29 is appended hereto as Attachment 2.

Claims 1 and 2 are directed to a method for the treatment of Alzheimer's disease, in a human, comprising administering to the human in need thereof an effective amount of an agent which increases the insulin sensitivity of the human, with the proviso that said agent is not insulin-like growth factor or a dopamine agonist.

Claim 25 is directed to a method for the treatment of Alzheimer's disease, in a human, comprising administering to the human in need thereof an effective amount of a thiazolidinedione which increases the insulin sensitivity of the human. Claim 21 specifies

that the thiazolidinedione is 5-[4-[2-(5-ethylpyridin-2-yl)ethoxyl]benzyl]thiadia-zolidine-2,4-dione (pioglitazone, see U.S. Pat. No. 5,478,852; Attachment 3). Claim 22 specifies that the thiazolidinedione is 5-[4-[2-(5-ethylpyridin-2-yl)ethoxyl]benzyl]thiadiazolidine-2,4-dione hydrochloride (pioglitazone hydrochloride). Claim 7 specifies that the thiazolidinedione is troglitazone.

III. The '154 Patent Claims Subject Matter That is the Same As Subject Matter Claimed in the Captioned Application

A. Claimed Subject Matter in the '154 Patent

Claims 1-5 of the '154 patent recite:

1. A method for treating Alzheimer's disease, comprising administering a therapeutically effective amount of at least one PPARγ agonist to a subject, wherein said PPARγ agonist is selected from the group consisting of troglitazone, ciglitazone, pioglitazone, BRL 49653 and englitazone.

2. The method of claim 1, wherein said subject is selected from the group consisting of subjects identified as being susceptible to Alzheimer's disease and subjects suffering from Alzheimer's disease.

3. The method of claim 1, wherein said therapeutically effective amount of said PPARγ agonist is between 0.1 mg to 100 mg.

4. The method of claim 1, wherein said therapeutically effective amount of said PPARγ agonist comprises approximately 10 mg/kg per day.

5. The method of claim 1, wherein said administering comprises oral administering.

B. Claimed Subject Matter in the Captioned Application

Claims 7, 21, 22 and 25 of the captioned application recite:

7. The method of claim 25, wherein said thiazolidinedione is troglitazone.

21. The method of claim 25, wherein said thiazolidinedione is 5-[4-[2-(5-ethylpyridin-2-yl)ethoxyl]benzyl]thiadiazolidine-2,4-dione. (pioglitazone)

22. The method of claim 25, wherein said thiazolidinedione is 5-[4-[2-(5-ethylpyridin-2-yl)ethoxyl]benzyl]thiadiazolidine-2,4-dione hydrochloride. (pioglitazone hydrochloride)

25. A method for the treatment of Alzheimer's disease, in a human, comprising administering to the human in need thereof an effective amount of a thiazolidinedione which increases the insulin sensitivity of the human.

IV. The Methods Claimed in the '154 Patent and Claimed in the Captioned Application are Substantially the Same Invention

Claim 1 of the '154 patent is directed to a method for treating Alzheimer's disease by administering, *inter alia*, troglitazone and pioglitazone. Claim 7 of the present application is directed to a method of treating Alzheimer's disease with troglitazone. Claim 21 of the present application is directed to a method of treating Alzheimer's disease with pioglitazone. Therefore, claim 1 of the '154 patent is directed to the same invention as claims 7 and 21 of the present application.

Dependent claim 2 of the '154 patent specifies that the subject is susceptible to Alzheimer's disease or suffering from Alzheimer's disease. Since the only two classes of individuals that would be treated for Alzheimer's disease are those susceptible to Alzheimer's disease or suffering from Alzheimer's disease, claim 2 does not further limit claim 1 and is not patentably distinct from claim 1.

Dependent claim 3 of the '154 patent specifies that the therapeutically effective amount of the compound is between 0.1 mg to 100 mg. Since this is a very broad range of dosage, claim 3 is not patentably distinct from claim 1.

Dependent claim 4 of the '154 patent specifies that the therapeutically effective amount of the compound comprises approximately 10 mg/kg per day. Since there is no evidence that this dosage imparts any unexpected results in the claimed method, claim 4 is not patentably distinct from claim 1.

Dependent claim 5 of the '154 patent specifies that the compound is administered orally. Since troglitazone and pioglitazone are orally active (see Attachment 3, col. 17, lines 24-35) and are normally administered orally for treatment of type 2 diabetes (see attachments 4 and 5, respectively), claim 5 is not patentably distinct from claim 1.

Therefore, claims 1-5 of the '154 patent define the same patentable invention as claims 7, 21, 22 and 25 of the present application.

V. The Captioned Application Should be Withdrawn for a Declaration of Interference With the '154 Patent

As discussed in the Request For Interference, the proposed count encompasses claims 7, 21, 22 and 25 of the captioned application, and claims 1-5 of the '154 patent. The proposed count is:

> A method for treating Alzheimer's disease, comprising administering a therapeutically effective amount of at least one PPARγ agonist to a subject, wherein said PPARγ agonist is selected from the group consisting of troglitazone, ciglitazone, pioglitazone, BRL 49653 and englitazone.

or

A method for the treatment of Alzheimer's disease, in a human, comprising administering to the human in need thereof an effective amount of a thiazolidinedione which increases the insulin sensitivity of the human.

In view of the foregoing and the Request For Interference filed herewith, Applicants respectfully request that the captioned application be withdrawn from issue as soon as possible, and that the application be referred to the Examiner for an evaluation of whether interfering subject matter is present between the captioned application and the '154 patent.

Prompt and favorable consideration of this Petition is earnestly solicited.

Respectfully submitted,

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Date: March 29, 2001

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Attachments

1 - U.S. Patent No. 6,191,154 B1
2 -Copy of allowed claims 1, 2, 7, 8 and 13-29
3 -U.S. Pat. 5,478,852
4 -Physician's Desk Reference, Medical Economics Company, Inc., Montvale, NJ, pp.2278-2282 (2000)
5 -Physician's Desk Reference, Medical Economics Company, Inc., Montvale, NJ, pp. 3088-3053 (2000)